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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,740	11/23/2007	Ralph A. Cowden III	4396-060415	6915

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EXAMINER	
MILLIGAN, ADAM C	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/571,740	COWDEN III ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10/22/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objection

Claims 1-9 and 11-13 stand objected to because of the following informalities: the phrase “at least every five out of every seven days” (emphasis added) is unclear as to what time period is being claimed. Examiner reiterates that the time period remains unclear where “every five out of every seven" is unclear if the time period relates to an on-going seven day regimen, requiring at least 5 days out of every 7 days, or simply every day for five days within a specific seven day period.

Claim Rejections - 35 USC § 103

Claims 1-3 and 11-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997, The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156).

Applicants' first assert that Rozema teaches away from oral administration of EDTA because Rozema states that only about 5% of orally administered EDTA is absorbed from the gastrointestinal tract and that the most effective route of administration appears to be intravenous. Applicants secondly assert that it would not have been obvious to one of ordinary skill in the art to combine the teachings of Kotilainen with Rozema because neither publication suggests such a combination.

Examiner disagrees. First, the fact that only a small percentage of orally administered EDTA is absorbed in the gastrointestinal tract is only of slight concern because as stated in the previous office action, the EDTA herein is being administered to remove heavy metals from tooth fillings which may have progressed through the digestive tract in order to chelate the heavy metals in the stomach or intestines prior to absorption of the heavy metals into the blood stream.

Even so, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Here, while oral administration is viewed as a non-preferred embodiment, the skilled artisan would recognize that even a 5% absorbance could provide therapeutic benefits after absorption as well, albeit a less preferred method. Therefore, Rozema is relied upon for all it teaches, including the lower absorbing oral administration form.

Second, it would have been further obvious to combine a mouthwash comprising EDTA and orally administered EDTA for the additional reason to more thoroughly

remove heavy metals from the entire digestive tract. A mouthwash is particularly helpful because teeth fillings in the mouth are a large source of heavy metals, but mouthwashes are not generally ingested. As such, the addition of an enteric coated EDTA provides an effective way to deliver EDTA to the intestinal track to remove heavy metals which may have progressed from the mouth to the intestinal tract.

With regard to new claims 11-13, Rozema further teaches that Vitamin C is a weak chelating agent and is synergistic with EDTA (p. 41, § g. Ascorbate). Vitamin C enhances the ability of EDTA to remove lead from the central nervous system (CNS) and also acts as an antioxidant and free radical scavenger (id.). Rozema also teaches that dimercaptosuccinic acid (DMSA) reacts with lead, mercury, arsenic and gold (p. 57-59, § B. DMSA- Succimer-Chemet). DMSA may be administered orally, generally daily, and is well absorbed by the body (id.).

It would have been obvious to one of ordinary skill in the art to include Vitamin C to the method discussed above in order to enhance the ability of EDTA to remove lead from the CNS as taught by Rozema. It would have also been obvious to include DMSA in order to remove heavy metals contaminates such as lead, mercury, arsenic and gold, as taught by Rozema.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents

for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156) and Rabussay (U.S. 4,355,022).

Applicants' did not present further arguments against the rejection of claim 4, and thus the rejection of record stands.

Claim 5-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156) and Hsia (U.S. 6,180,139).

Applicants' first argue that Hsai fails to teach lecithin in the absence of an antioxidant and a vitamin B complex and that Hsai does not teach lecithin administered orally with a mouthwash or together with oral EDTA. Applicants' second argue that Hsai teaches a treatment for nonalcoholic steatohepatitis, which is a condition different and distinct from those of Rozema, Kotilainen, and the present invention. Applicants' argue that there is no suggestion in the references to combine the mouthwash and oral administration for as suggested by the Examiner when considering the claimed invention as a whole.

Examiner disagrees. First, instant claims 5-7 require only an additional dose of phosphatidyl lipids. Hsai teaches such a dose of phosphatidyl lipids. Examiner maintains the composition of the prior art reads on the composition of the claim 5, given

the use of the open ended transition phrase “comprising" which allows for the inclusion of additional components, such as antioxidants and a vitamin B complex.

Second, Lecithin is taught by Hsai to increase brain function and neurological activity (Hsai at ¶17). Lecithin is also taught to increase absorption in the digestive tract and to treat exposure to toxic chemicals (id.). Thus it would have been obvious to one of ordinary skill in the art to combine lecithin into the heavy metal treatment protocol rendered obvious by Rozema and Kotilainen in order to (1) increase brain function which may have been impaired by heavy metal contamination, (2) increase the absorption of EDTA in the digestive system, and (3) treat overexposure to the toxic heavy metals.

Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156), Hsia (U.S. 6,180,139), and Hermann (Enantioselective pharmacokinetics and bioavailability of different racemic α-lipoic acid formulations in healthy volunteers, European Journal of Pharmaceutical Sciences. Vol. 4, pp. 167-174, 1996).

Applicants’ did not present further arguments against the rejection of claim 8, and thus the rejection of record stands.

Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Rozema (Journal of Advancement in Medicine, Vol. 10, No. 1, Spring 1997 (The Protocol for the Safe and Effective Administration of EDTA and Other Chelating Agents for Vascular Disease, Degenerative Disease, and Metal Toxicity) in view of Kotilainen (U.S. 4,885,156), Hsia (U.S. 6,180,139), Hermann (Enantioselective pharmacokinetics and bioavailability of different racemic α-lipoic acid formulations in healthy volunteers, European Journal of Pharmaceutical Sciences. Vol. 4, pp. 167-174, 1996), and Yasahiro (JP 62012721) (English text summary attached).

Applicants' did not present further arguments against the rejection of claim 9, and thus the rejection of record stands.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/A. M./
Examiner, Art Unit 1612